

Appl. No. 10/078,042
Docket No. 8430L
Amdt. dated October 20, 2008
Reply to Office Action mailed on May 19, 2008
Customer No. 27752

REMARKS

Claim Status

Claims 1-10 and 14-30 are pending in the present application.

Claims 11-13 were previously canceled without prejudice.

Claims 1, 6-10 and 16-20 have been amended. Support for the substantive amendments to independent claims 1, 6, 8 and 9, is found in the specification at page 12 (sampling strategy). The remaining amendments are non-substantive, made only for purposes of form.

Claims 21-30 are new. Support for these new claims is found within the originally submitted claims (selections of elements from original Markush groups); and in the Specification at page 18 (use of target); and at page 19, line 26 to page 20, line 15 (multi-variate analysis of variable data and attribute data).

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejections Under 35 USC §103(a)

Under MPEP §2142, the Office bears the burden of factually supporting an asserted *prima facie* conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537; 218 U.S.P.Q. 871 (Fed. Cir. 1983). If the Office does not demonstrate *prima facie* unpatentability, then without more, the Applicant is entitled to the grant of the patent. *See In re Oetiker*, 977 F.2d 1443, 1445; 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must show that all of the claim elements are taught or suggested in the prior art. *See, e.g.,*

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CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1342; 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003).

Office Action Paragraph 3 – Claims 1, 2, 5, 9, 10 and 14-20

Claims 1, 2, 5, 9, 10 and 14-20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Sheehan et al. (USPN 6,319,199) in view of Frasca, Jr. (USPN 6,055,506) and in further view of Walker et al. (USPN 5,828,751). Applicants respectfully traverse the rejection.

A. Claims 1, 2 and 5

Without conceding the merits of the rejection Applicants have amended Claim 1. Claim 1, as amended, recites a system to improve the management of an individual's health, the system including: a) a data measurement mechanism generating data relevant to a particular physical health condition of the individual; b) a data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium, wherein the data acquisition mechanism and the data measurement mechanism are disposed on a single handheld device; c) at least one data analysis mechanism generating information pertaining to the physical health of the individual wherein the data analysis mechanism performs at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy, the analysis selected from the group consisting of: statistical control chart techniques multi-variate analysis, attribute data analysis, and reliability engineering analysis; and d) an information presentation mechanism displaying the information pertaining to the physical health of the individual. By dependency, Claims 2 and 5 include all of these elements.

1. The Cited References Do Not Teach An Analysis Based On Historical Or Recent Health Data Of An Individual Collected In Accordance With A Sampling Strategy.

Without conceding the merits of the rejection in any other respect or waiving any other arguments they may have, Applicants submit that neither Sheehan et al., Frasca, Jr., nor Walker et al., alone or in combination, recite a system that includes a data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy.

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2. The Cited References Do Not Teach a Data Analysis Mechanism That Performs At Least One Analysis Selected From The Group Consisting Of: Statistical Control Chart Techniques, Multi-Variate Analysis, Attribute Data Analysis, and Reliability Engineering Analysis.

Without conceding the merits of the rejection in any other respect or waiving any other arguments they may have, Applicants submit that neither Sheehan et al., Frasca, Jr., nor Walker et al., alone or in combination, recite a system that includes a data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual, selected from the group consisting of: statistical control chart techniques, multi-variate analysis, attribute data analysis, and reliability engineering analysis.

At Paragraphs 3(A) and 8(2) of the Office Action dated May 19, 2008, the Office asserts that Frasca, Jr. teaches attribute data analysis, thereby teaching that particular element of the Markush group in the claim. Applicants respectfully disagree. The “attribute” discussed in the passage from Frasca, Jr. upon which the Office relies is a patient’s temperature. (Frasca, Jr. col. 13, l. 58 – col. 14, ll. 1-6.) Patient temperature is not an example of “attribute data” within the meaning of Applicants’ claims.

Applicants have expressly defined “attribute data” as *qualitative* data, distinguished from “quantitative data”, as follows:

Quantitative measurements of health or environmental parameters are referred to herein as “variables”, while qualitative observations are referred to as “attribute” data. Variables may include any measured numerical data related to a health event, medical condition, the individual’s demographics, or environmental or other data such as dietary components and ambient conditions (e.g., temperature, barometric pressure, pollen and mold counts, smog or other air pollution data, and the like). Attributes may include qualitative ratings, questionnaire responses, visual images (e.g., digital images), causes of a health event or medical condition, remedies or treatments for a health event or medical condition, environmental or other potentially relevant information, such as diet, activity, and medical history. Attributes may also include demographic data. Demographics may comprise variables and attributes including an individual’s age, gender, race, geographical location, medical history, current medical conditions,

symptoms, or health events, vocation, stress factors, psychographic or temperament data, and any other descriptive information related to the individual, their family, or environment.

(Specification, p. 9, line 31 – p. 10, line 5.) Where an explicit definition is provided by the applicant for a claim term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). *See also* MPEP § 2111.01 IV.

In Applicants' specification, a patient's temperature is deemed an item of *quantitative* data. (See Specification at p. 5, lines 24-26.) It is, therefore, not "attribute data" as that term is used in Applicants' claims. Consequently, Frasca, Jr. does not teach or suggest a system that includes a data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual, selected from the group consisting of: statistical control chart techniques, multi-variate analysis, *attribute data* analysis, and reliability engineering analysis.

* * *

For the foregoing reasons, Applicants respectfully submit that the combination of Sheehan et al., Frasca, Jr. and Walker et al. does not teach or suggest all of the elements of Applicants' amended Claim 1 (nor Claims 2 and 5, which by dependency include all of the elements of Claim 1), and therefore, does not provide support *a prima facie* conclusion of obviousness of these claims. Applicants respectfully request reconsideration and withdrawal of the rejection.

B. Claims 9, 10 and 14-20

Without conceding the merits of the rejection, Applicants have amended Claim 9. Claim 9, as amended, recites a method for improving the health of an individual including the steps of: a) selecting at least one health parameter appropriate for the individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional; b) creating a sampling strategy for measuring the at least one health parameter of interest; c) measuring the at least one health parameter of interest and pertinent environmental or qualitative information according to the sampling strategy to produce data; d) acquiring the data for

storage and subsequent analysis; e) analyzing the data via at least one data analysis mechanism to define at least one of an out-of-control situation requiring intervention and potential causes or remedies of an out-of-control situation wherein the data analysis mechanism performs at least one analysis based on the historical or recent health data of the individual, selected from the group consisting of: statistical control chart techniques, multi-variate analysis, attribute data analysis, and reliability engineering analysis; and f) presenting the information to the individual, caregiver, or medical professional. By dependency, Claims 10 and 14-20 include all of the elements of Claim 9.

Without conceding the merits of the rejection in any other respect or waiving any other arguments they may have, Applicants submit that neither Sheehan et al., Frasca, Jr., nor Walker et al., alone or in combination, recite a method that includes the step of creating a sampling strategy for measuring at least one health parameter of interest.

Without conceding the merits of the rejection in any other respect or waiving any other arguments they may have, Applicants submit that neither Sheehan et al., Frasca, Jr., nor Walker et al., alone or in combination, recite a method that includes the step of analyzing data via at least one data analysis mechanism that performs at least one analysis selected from the group consisting of: statistical control chart techniques, multi-variate analysis, attribute data analysis, and reliability engineering analysis. *See* Part A.2, *supra*, which is incorporated herein by reference.

For the foregoing reasons, Applicants respectfully submit that the combination of Sheehan et al., Frasca, Jr. and Walker et al. does not teach or suggest all of the elements of Applicants' amended Claim 9 (nor Claims 10 and 14-20, which by dependency include all of the elements of Claim 9), and therefore, does not provide support a *prima facie* conclusion of obviousness of these claims. Applicants respectfully request reconsideration and withdrawal of the rejection.

Office Action Paragraph 4 – Claims 6 and 7

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Sheehan et al. in view of Frasca, Jr. in view of Walker et al. and in even further view of Litt et al. (USPN 6,658,287). Applicants respectfully traverse the rejection.

Without conceding the merits of the rejection, Applicants have amended Claim 6. Claim 6, as amended, recites a system to improve the management of an individual's health, the system including a) a handheld data measurement mechanism generating data relevant to a particular health condition; b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group consisting of: a tablet PC, voice recognition, and telemetry based systems; c) at least one data analysis mechanism generating information pertaining to the health of the individual, wherein the data analysis mechanism performs at least one statistical control chart analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy; and d) an information presentation mechanism displaying the information pertaining to the health of the individual, the displayed information comprising a statistical control chart based on the historical or recent health data of the individual. By dependency, Claim 7 includes all of the elements of Claim 6.

Without conceding the merits of the rejection in any other respect or waiving any other arguments they may have, Applicants submit that neither Sheehan et al., Frasca, Jr., Walker et al., nor Litt et al., alone or in combination, recite a system that includes at least one data analysis mechanism that performs at least one statistical control chart analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy.

Further,

To establish a *prima facie* case of obviousness, [the proponent – here, the Office] must show "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." [*In re* *Fine*, 837 F.2d at 1074, 5 U.S.P.Q.2D (BNA) at 1598. There is no suggestion to combine, however, if a reference teaches away from its combination with another source. *See id.* at 1075, 5 U.S.P.Q.2D (BNA) at 1599. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2D (BNA) 1130, 1131 (Fed. Cir. 1994). If when combined, the

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references "would produce a seemingly inoperative device," then they teach away from their combination. *In re Spinnoble*, 56 C.C.P.A. 823, 405 F.2d 578, 587, 160 U.S.P.Q. (BNA) 237, 244 (CCPA 1969); *see also In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. (BNA) 1125, 1127 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose).

Tec Air, Inc. v. Denso Mfg. Michigan Inc., 192 F.3d 1353, 1359-1360; 52 U.S.P.Q.2d 1294 (Fed. Cir. 1999). "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448, 230 U.S.P.Q. 416 (Fed. Cir. 1986), *quoting In re Wesslau*, 353 F.2d 238, 241, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965).

Litt et al. teaches a method and apparatus for predicting the onset of epileptic seizures. In seeking to further combine the teachings of Litt et al. with the combination of Sheehan et al., Frasca, Jr. and Walker et al., the Office appears to have ignored that Litt et al. teaches a system in which brain activity signals are continuously monitored via electrodes implanted in the patient's brain, and in which a processing device is implanted elsewhere in the patient's body. (Litt et al., col. 5, lines 14-16; col. 5, line 65 – col. 6, line 6.) Modifying the teachings of Litt et al. so as to fall within Applicants' Claim 6 would require rendering the system of Litt et al. inoperative for its intended purpose, because, for example, it would require moving Litt et al.'s data measurement system (including the implanted electrodes) to a handheld mechanism. Thus, the teachings of Litt et al. may not properly be combined with Sheehan et al., Frasca, Jr. and Walker et al. to support a *prima facie* case of obviousness of Applicants' Claim 6.

For the foregoing reasons, Applicants respectfully submit that the combination of Sheehan et al., Frasca, Jr., Walker et al. and Litt et al. does not teach or suggest all of the elements of Applicants' amended Claim 6 (nor Claim 7, which by dependency includes all of the elements of Claim 6), and therefore, does not provide support a *prima facie* conclusion of obviousness of these claims. Further, Applicants respectfully submit that Litt et al. may not properly be combined with the other references to support a *prima facie* case. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

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Office Action Paragraph 5 – Claim 8

Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Sheehan et al. in view of Frasca, Jr. in view of Walker et al. and in further view of Falcone (USPN 5,464,012) and in even further view of Zadrozny et al. (USPN 6,540,674). Applicants respectfully traverse the rejection.

Without conceding the merits of the rejection, Applicants have amended Claim 8. As amended, Claim 8 now recites a system to improve the management of an individual's health, the system including: a) a data measurement mechanism generating data relevant to a particular health condition of the individual; b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium, the data acquisition mechanism being adapted to perform a preliminary analysis on the data and provide an output when the data comprises a value that is outside of a target; c) at least one data analysis mechanism generating information pertaining to the health of the individual, wherein the data analysis mechanism performs at least one statistical control chart analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy, the information including at least one level of intervention when an out-of-control condition requiring intervention has been measured; and d) an information presentation mechanism displaying to the individual the information pertaining to the health of the individual, wherein the at least one information presentation mechanism is selected from the group consisting of: a graphical summary screen, an icon based summary screen, a help guide, and anthropomorphic help guide, and synthesized speech.

Without conceding the merits of the rejection in any other respect or waiving any other arguments they may have, Applicants submit that neither Sheehan et al., Frasca, Jr., Walker et al., Falcone, nor Zadrozny et al., alone or in combination, recite a system that includes a data analysis mechanism that performs at least one statistical control chart analysis based on historical or recent health data of the individual, nor one in which such data is collected in accordance with a sampling strategy.

For the foregoing reasons, Applicants respectfully submit that the combination of Sheehan et al., Frasca, Jr., Walker et al., Falcone, and Zadrozny et al. does not teach or

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suggest all of the elements of Applicants' amended Claim 8, and therefore, does not provide support a *prima facie* conclusion of obviousness of the claim. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

Office Action Paragraphs 6 and 7

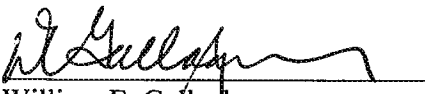
Paragraph 6 and 7 of the Office Action dated May 19, 2008 address only dependent claims 3 and 4. As set forth above, Applicants believe and submit that independent Claim 1 is patentable over the references cited. If independent Claim 1 is patentable, then dependent Claims 3 and 4, being narrower, are also patentable. Therefore, Applicants respectfully defer argument concerning Paragraphs 6 and 7 of the Office Action in the instant response.

Conclusion

This response represents an earnest effort to place the present application in proper form for allowance. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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